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Jane Bradd Andersen, Regulatory Affairs
DuPont Engineering Polymers
Chestnut Run Plaza
Building 702, Room 2009C
4417 Lancaster Pike
Wilmington, DE 19805

DEC 11 2009

Re: PMN-08-508 and 509

Dear Ms. Andersen:

The Environmental Protection Agency ("EPA") has reviewed the submitted protocols for the Avian Reproductive Toxicity Study on the chemical substance, P08-509 described in the above-referenced consolidated premanufacture notice ("PMN"). This study is required by EPA, under the authority of §5(e) of the Toxic Substances Control Act ("TSCA"), before you may exceed the production volume specified in the Consent Order governing this PMN substance.

EPA's comments and recommendations on the proposed protocols are designed to avoid potential problems so that the results of the study will be scientifically valid test data. Under no circumstance does approval of the test protocol mean pre-acceptance of test results.

The protocols include a pilot study and a definitive study. Basically, EPA finds the method for the pilot study to be suitable. However, exposure to the test substance for 10-weeks prior to egg laying would better reflect exposure durations used in the definitive study and would provide a better basis for selection of test concentrations for the definitive study. Also, EPA offers the following additional comments. Test concentrations chosen for the definitive study should result in a least 3 surviving treatment groups from which a NOAEL and LOAEL can be determined. For the definitive study, in order to comply with OPPTS 850.2300, at least a 10 week long exposure to parental bobwhite quail is needed prior to egg laying. Additionally, test substance name, CAS number, and composition (degree of purity and percentage of each impurity) need to be provided in the study reports and a Certificate of Analysis submitted.

The test substance is considered to be persistent and thus, "[a]nalysis of two or more tissues (e.g., muscle, fat) for the test substance residues is ... required" according to OPPTS 850.2300. Based on the results of the study of mallards and quails by Newstad et al. (2007), analysis of test substance concentrations from parent and offspring in blood serum and livers is recommended. Analysis of test substance concentrations in albumin, yolks, shell, and membrane from eggs of P-08-509 would also be beneficial.

CONCURRENCES

SYMBOL	7405	7405			
SURNAME	Clifton	Thurston			
DATE	12/9/09	12/10/09			

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If you have any questions or comments, please contact me at (202) 564-8970.

Sincerely,

/S/

Rose Allison, Senior Specialist
New Chemicals Notice Management Branch
Chemical Control Division (7405 M)

References

Newstad J.L., Coady K.K., Beach S.A., Butenhoff J.L., Gallagher S., Giesy J.P. 2007. Effects of perfluorooctane sulfonate on mallard and northern bobwhite quail exposed chronically via the diet. Environmental Toxicology and Pharmacology, 23: 1-9.

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